K103416

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MAR 17 2011

Section 3: 510(k) Summary

Date Prepared: 11/19/2010

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Quality Assurance Manager

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Submitter Name: InfiMed, Inc.
121 Metropolitan Drive
Liverpool, NY 13088

Device Trade Name: Nexus DRF Digital X-ray Imaging System

Common Name: Digital X-ray Imaging System

Classification Name(s):		**Product Codes:**
Nexus DRF Digital X-ray Imaging System		JAA, MQB, DWB
Predicate Device:	**510(k) Number:**	**Product Codes:**
i^5™ Digital X-ray Imaging System	K093066	JAA, MQB

Device Description:

The InfiMed i^5™ Digital X-ray Imaging System is a high resolution digital imaging system designed for digital X-ray imaging through the use of an X-ray detector. The InfiMed i^5™ Digital X-ray Imaging System is designed to support general radiography (excluding mammography), fluoroscopy, interventional fluoroscopy or angiography imaging procedures through a single common imaging platform.

The modified InfiMed i^5™ Digital X-ray Imaging System consists of an X-ray imaging receptor (any of the following: CCD Camera, Trixell Pixium 3543, Trixell Pixium 4600, Varian PaxScan 4336R, Varian PaxScan 4343R, Carestream Health Detector, Samsung LTX240AA01-A, Toshiba FDX 4343R, Trixell Pixium RF4343), computer, monitor, and the digital imaging system.

Intended Use:

The i^5™ Digital X-ray Imaging System is a high resolution digital imaging system intended to replace conventional film techniques, or existing digital systems, in multipurpose or dedicated applications specified below. The i^5™ Digital X-ray Imaging System enables an operator to acquire, display, process, export images to portable media, send images over a network for long term storage and distribute hardcopy images with a laser printer. Image processing algorithms enable the operator to bring out diagnostic

details difficult to see using conventional imaging techniques. Images can be stored locally for temporary storage. The i^5™ Digital X-ray Imaging System has the ability to interface with a variety of image receptors from CCD cameras to commercially available flat panel detectors. The major system components include an image receptor, computer, monitor and imaging software.

For the DR application, the InfiMed i^5™ Digital X-ray Imaging System is intended for use in general radiographic examinations and applications (excluding fluoroscopy, angiography, and mammography).

For the RF/DSA application, the InfiMed i^5™ Digital X-ray Imaging System is intended for use where general fluoroscopy, interventional fluoroscopy or angiography imaging procedures are performed.

Technological Characteristics Comparison:

The modified device supports the same modalities as the predicate device with the same components or imaging concepts, and delivers equivalent or better image quality as the predicate device. The comparison chart reveals that functions performed by the predicate device are performed by the modified i^5™ Digital X-ray Imaging System. The modified device, Nexus DRF Digital X-ray Imaging System, also has the ability to interface with an additional image receptor, Trixell Pixium RF4343. Therefore, the modified device is substantially equivalent to the predicate device.

Non-clinical Tests Discussion:

Validation was completed in accordance with the Validation Protocols included with this submission. Protocols were designed, executed and documented according to the Design Validation process with predetermined test methods and corresponding acceptance criteria. In conclusion, all release criteria have been met and the modified i^5™ Digital X-ray Imaging System is as safe and effective as the predicate device.

Clinical Tests Discussion:

Clinical Data submitted is consistent with FDA guidance document "Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance: Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" available at the website http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073781.pdf.

Conclusion:

Based upon the results of Verification and Validation testing, the Nexus DRF Digital X-ray Imaging System has no new indications for use, has no significant technological

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differences, and is as safe and effective as, and therefore substantially equivalent to the above listed current legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

InfiMed, Inc.
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Consultant
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JUL 30 2012

Re: K103416
Trade/Device Name: Nexus DRF Digital X-Ray Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA, and MQB
Dated: November 19, 2010
Received: November 22, 2010

Dear Mr. Shah:

This letter corrects our substantially equivalent letter of March 17, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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Section 2: Indications for Use

510(k) Number (if known): K103416

Device Name: Nexus DRF Digital X-ray Imaging System

Indications for Use:

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

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